HFI-35

Public Health Service

FOOD & DRUG ADMINISTRATION 466 FERNANDEZ JUNCOS AVENUE SAN JUAN, P.R. 00901-3223

April 3, 1997

WARNING LETTER SJN-97-10

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. Carlos Colón Guzmán President GMD Airline Services P.O. Box 37667 Airport Station San Juan, Puerto Rico 00937-7667

Dear Mr. Colón:

During an inspection of your airline watering point at Gate 38, Luis Muñoz Marin International Airport, Carolina, Puerto Rico conducted on April 2, 1997, our inspectors found deficiencies which are considered violations of the Public Health Service Act and the Interstate Conveyance Sanitation Regulations; title 21, Code of Federal Regulations, 1240.83 (21 CFR 1240.83).

Observations as listed on the Inspectional Observations (FDA Form 483) included, but were not limited to the following deviations:

- 1. There is no backflow prevention device on the water system. This is a critical deviation.
- The end of the water hose is not protected with a permanently affixed cap and keeper chain. The end of the hose was in contact with the unclean floor of the cabinet.
- The rise from ground to cabinet floor is only about 3 in. The water drain is not properly covered, and the cabinet is not fully enclosed.
- 4. The water pressure gauge was nonfunctional and rusty.

The observations were discussed with Mr. Julio Colón, Asst. Vice President, at the close of the inspection. A copy of the FD-483 is included for your review.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each applicable requirement of the Public Health Service Act and applicable regulations.

As a result of these observations, your watering point is classified "NOT APPROVED" for servicing interstate carriers. A re-inspection will be conducted as soon as you respond to determine if corrections have been accomplished.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 466 Fernandez Juncos Avenue, Puerta de Tierra, San Juan, Puerto Rico 00901-3223, Attention: John M. McInnis, Compliance Officer.

If you require any assistance in understanding the contents of this letter, or if you desize a meeting with members of our staff, please contact Mr. McInnis, at (787) 729-6894.

Copies of this letter are being sent to Dr. Hernan Sulsona, Director, Puerto Rico Ports Authority, and to each of the agents that use this watering point facility.

Sincerely,

District Director

Enclosure: FDA Form 483 as noted

cc:

Dr. Hernan Sulsona Director Puerto Rico Ports Authority P. O. Box 362829 San Juan, Puerto Rico 00936-2829